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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,587

04/18/2006

Jean Krutmann

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3294

62836 7590 04/13/2009

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EXAMINER

SIMMONS, CHRIS E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

04/13/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,587	<b>Applicant(s)</b> KRUTMANN, JEAN	
	<b>Examiner</b> CHRIS E. SIMMONS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6,9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) 1,2 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6,9 and 10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

Applicant's arguments, see pages 4-5, filed 02/04/2009, with respect to all pending claims have been fully considered and are persuasive. The rejection of 08/05/2008 has been withdrawn.

### ***New Claim Rejections***

#### ***35 USC § 103***

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1612

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/036915 in view of Pichereau et al. (Microbiology (1999);145:427-435).

The primary reference relates to methods and compositions useful for hydrating airway surfaces and treating airway diseases. It provides methods for treating chronic obstructive pulmonary disease in a subject in need of such treatment. The method comprises administering a non-absorbable, osmotically active compound such as a salt, sugar, sugar alcohol, organic osmolyte, or other osmotically active compound to an airway surface of the subject in an amount effective to increase the volume of fluid on the airway surface (abstract). The active compounds of the present invention may be administered in aqueous or non-aqueous (e. g., solid particulate) form or in liquid form

Active compounds of the invention, used either as active compounds alone, or as active compounds used in conjunction with other kinds of active agents (e. g., bronchodilators, purinergic receptors, antibiotics, enzymes, anti-inflammatory agents, etc.), may be administered to airway surfaces (including nasal surfaces) by any suitable means, such as by droplets, sprays, aerosols of respirable or non- respirable particles, or transbronchoscopic lavage. The active compounds of the invention may be administered in aqueous or non-aqueous (e. g., solid particulate) form. (p. 3, ll. 1-8) or in liquid form (p. 2, ll. 29-34). Aerosols of liquid particles comprising the active compound may be produced by any suitable means, such as with a pressure-driven aerosol

Art Unit: 1612

nebulizer or an ultrasonic nebulizer. Powders may be administered using metered dose inhalers.

Organic osmolytes useful as active compounds in the invention include but are not limited to three major classes of compounds: polyols (polyhydric alcohols), methylamines, and *amino acids* (pg. 6, ll. 10-12). Mammalian organic osmolytes are preferred, with human organic osmolytes being most preferred. However, certain organic osmolytes are of bacterial, yeast, and marine animal origin, and these compounds are also useful active compounds within the scope of the invention (pg. 6, ll. 21-24).

The secondary reference discloses ectoine as an osmoprotectant that did not allow the level of growth of stressed *E. coli* cells to non-stressed levels. The reference does not expressly teach an inhaler containing osmolytes (abstract; pg. , 1<sup>st</sup> paragraph).

It would have been obvious to one of ordinary skill in the art to use the ectoine osmolyte from the secondary reference as the osmolyte in the primary reference.

The artisan would have been motivated by the reasonable expectation of successfully making an inhaler containing ectoine that would be effective for administering the osmolyte to treat lung diseases such as COPD. Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. *MPEP* § 2144.07. Accordingly, it would have been obvious to replace the primary osmolyte with another known osmolyte such as ectoine.

***Conclusion***

No claims are allowed.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1612

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. S./  
Examiner, Art Unit 1612

***/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612***